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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,700	01/26/2004	Jeanne F. Loring	PA-0024-1 CON	1144

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EXAMINER	
LIU, SUE XU	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,700	LORING ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a composition comprising a plurality of cDNA selected from SEQ ID Nos 1-138, classified variously, for example in class 536, subclass 23.1.

II. Claims 7 and 7 (Note the duplicity in Claim numbers), drawn to a method of detecting differential expression of one or more cDNA in a sample, classified variously, for example in class 435, subclass 6.

III. Claims 8 and 9, drawn to a method of identifying a ligand that specifically binds to a cDNA, classified variously, for example in class 536, subclass 23.5.

IV. Claims 10-12, drawn to an isolated cDNA, classified variously, for example in class 536, subclass 23.1.

V. Claim 13, drawn to a method of producing a protein, classified variously, for example in class 435, subclass 70.1+.

VI. Claim 14, drawn to a protein product, classified variously, for example in class 530, subclass 350+.

VII. Claims 15 and 16, drawn to a method for using a protein to screen a library of molecules, classified variously, for example in class 530, subclass 412+.

VIII. Claim 17, drawn to a method of purifying a ligand from a sample, classified variously, for example in class 530, subclass 12+.

IX. Claim 18, drawn to a pharmaceutical composition, classified variously, for example in class 424, subclass 184.1+.

X. Claim 19, drawn to a method of producing an antibody using a protein, classified variously, for example in class 435, subclass 69.6.

Further Restriction (Note: This is not species selection.)

The inventions listed as Groups I-X are subjected to further restrictions as set forth below:

a. If applicants elect a Group of invention (such as Group I, II, or III) that reads on a combination (or a plurality) of cDNAs (or SEQ ID Nos), applicants are further requested to select a single specific combination of SEQ ID Nos for the plurality of cDNAs, i.e. Applicants are requested to specify the specific SEQ ID Nos in the selected COMBINATION of cDNAs.

b. If applicants elect a Group of invention (such as anyone of the Groups IV-IX) that reads on a single isolated cDNA (or SEQ ID Nos), applicants are further requested to select a single specific nucleic acid sequence identified by its corresponding SEQ ID NO.

The "Further Restrictions" are deemed proper since each one of the restrictions would result in an amino acid sequence or a nucleic acid sequence that possesses distinct function and/or structures. Thus, these different peptides or nucleic acids would have different modes of operation, different effects, and can be used in different methods. In addition, a search of multiple sequences would impose undue search burden on the office. See [MPEP 803.04 [R-3]

* Nucleotide Sequences] for restriction of nucleic acid sequences.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I, IV, VI, and IX are unrelated and represent patentably distinct products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions of Groups I, IV, VI, and IX are drawn to distinct products because they differ in respect to their properties, their use and/or method of making. Group I is drawn to a plurality of nucleic acid sequences with different structures and functions; Group IV is drawn to an isolated cDNA with different structure and function from Group I product; Group VI is drawn to a protein that is structurally and functionally different from Groups I and II; Group IX is drawn to a pharmaceutical composition that can comprise structurally and functionally different products from Groups I, IV and VI. Art anticipating or rendering obvious each of the above identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I, IV, VI, and IX have different issues regarding patentability and enablement and represent patentably distinct subject matter. Thus, restriction is proper.

3. Inventions of Groups II, III, V, VII, VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions in Groups II, III, V, VII, VIII and X direct to various distinct methods, because they use different steps, require different reagents and/or will produce different results. The invention of Group III directs to a method of identifying a ligand in a sample, and requires the step of "identifying a ligand that specifically binds to each cDNA", which are step and/or reagent that are not required by any other method groups. Groups V, VII, VIII and X are drawn to methods of making or using proteins, which are structurally and functionally different from Groups II and III. Each of the methods of Groups V, VII, VIII and X are different from each other because they use different steps and/or reagents that are not required by the other groups. Thus, inventions of Groups II, III, V, VII, VIII and X are distinct, and restriction between the groups is proper.

4. Inventions of Groups (I, IV, VI, and IX) and Groups (II, III, V, VII, VIII and X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different methods described in Groups II, III, V, VII, VIII and X can make and/or use different compositions from the compositions recited in each of the Groups I, IV, VI, and IX. For example, Group VIII could use either Group I or Group VI products. Each of the products could also be used in different process than the methods of Groups II, III, V, VII, VIII and X. For example, Group I product such as yeast two hybrid system to screen for interacting proteins within the cDNA library. Thus, restriction among the groups is proper.

5. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed invention. Applicants are requested to further elect **a single ultimate species for <u>each</u>** of the following:

A.) If applicants elect a Group of invention (such as Group I, II, or III) that reads on a combination (or a plurality) of cDNAs (or SEQ ID Nos), applicants are further requested to select a single specific SEQ ID No. for examination purposes. See [MPEP 803.04 [R-3] * Nucleotide Sequences], especially the example section.

B.) A single specific species of a disorder.

C.) A single specific species of a substrate.

D.) A single specific stage of Alzheimer's disease.

E.) A single specific species of a ligand.

F.) A single specific species of a library of compounds.

G.) A single specific selection of a protein **<u>OR</u>** a portion thereof.

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
3/30/06

MARK SHIBUYA, PH.D.
PATENT EXAMINER